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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,588

02/10/2006

Petra Lutter

12874-00013-US

3511

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05/26/2009

CONNOLLY BOVE LODGE & HUTZ, LLP

P O BOX 2207

WILMINGTON, DE 19899

EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,588	<b>Applicant(s)</b> LUTTER ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1–26 are pending.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

5           This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

          In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

10          Group I, claim(s) 1–11 and 20–26 (in part), drawn to a CD4+CD25+ T cell comprising galectin-10.

          Group II, claim(s) 12–19 and 20–26 (in part), drawn to a binding agent that binds a CD4+CD25+ T cell comprising galectin-10.

15          The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of group I is a CD4+CD25+ T cell comprising galectin-10. The special technical feature of group II is a  
20          binding agent that binds a CD4+CD25+ T cell comprising galectin-10. Clearly, the special technical features are not the same. In order for the inventions of groups I and II to have unity of invention it is necessary that the inventive concept be a contribution over the prior art. However, the international search report filed with the present application indicates that groups I and II cannot be considered novel or cannot be considered to involve an inventive concept. Therefore, the inventions of groups I and II do not fulfill the requirements for unity of invention.

25           This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

          The species are as follows:

30          an antibody that binds galectin-10 and CD25;

          an antibody that binds galectin-10 and CD44;

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- an antibody that binds galectin-10 and CD45;
- an antibody that binds galectin-10 and GITR;
- an antibody that binds galectin-10 and CTLA-4;
- an antibody that binds galectin-10 and Fox P3.

5           Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10           Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15           The claims are deemed to correspond to the species listed above in the following manner:  
claims 12–19 correspond to the species.

20           The following claim(s) are generic: claims 12–19.

25           The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species share the same structural feature, which is an antibody that binds galectin-10. However, Leiferman (J Immunol. 1986 Feb 1;136(3):852-5) discloses specific antibodies to CLC/galectin-10 (Abstract). Therefore, the species cannot be considered to involve an inventive concept. Therefore, the species do not fulfill the requirements for unity of invention.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5       The species are as follows:

          rheumatoid arthritis, multiple sclerosis, Crohn's disease, asthma, AIDS, transplant rejection, cancer, diabetes, alopecia areata, Bechterew's disease, antiphospholipid syndrome, Addison's disease, Behcet's disease, sprue celiac disease, chronic fatigue immune dysfunction syndrome (CFIDS), polyneuropathy, Churg-Strauss syndrome (granulomatosis), CREST  
10   syndrome (Raynaud's syndrome), cold agglutinin disease, cryoglobulinemia, fibromyalgia, fibromyositis, Basedow's disease, Guillain-Barre syndrome, idiopathic pulmonary fibrosis, idiopathic thrombocytopenia, IgA nephropathy, lichen planus, Meniere's disease, polyarteritis nodosa, polychondritis, polyglandular syndrome, polymyalgia rheumatica, primary  
15   agammaglobulinemia, biliary cirrhosis, psoriasis, Reiter's disease, sarcoidosis, Sjogren's disease, Takayasu arteritis, vasculitis, vitiligo and Wegener's granulomatosis.

          Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An  
20   argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

          Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

- 5     claims 18, 19, 25 and 26 correspond to the species.

The following claim(s) are generic: claims 18, 19, 25 and 26.

- 10     The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of claims 25 and 26 is a CD4+CD25+ T cell comprising galectin-10. However, Leiferman (J Immunol. 1986 Feb 1;136(3):852-5) discloses specific antibodies to CLC/galectin-10 (Abstract). Therefore, the species cannot be considered to involve an inventive concept. Therefore, the species do not  
15     fulfill the requirements for unity of invention.

          This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- 20           The species are as follows: SEQ ID NOs: 1, 2, 6 and 8-64.

- Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive  
25     unless accompanied by an election.

          Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

- 5     claims 1, 5 and 6 correspond to the species.

The following claim(s) are generic: claims 1-11.

- 10     The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: According to the specification SEQ ID NOs: 8-64 are isoforms of SEQ ID NO: 1 and 2 (Specification, page 5). However, Ackerman (J Immunol. 1993 Jan 15;150(2):456-68.) discloses the amino acid sequence of SEQ ID NO: 1. Therefore, the species cannot be considered to involve an inventive concept. Therefore, the species do not  
15     fulfill the requirements for unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

- 20     The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 25     Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

- 30     ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH

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FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/  
PRIMARY EXAMINER, ART UNIT 1647

DSR  
MAY 19, 2009